

**DRAFT – FOR DISCUSSION PURPOSES ONLY
REMARKS**

The Office Action of August 8, 2007, has been received and reviewed. Claims 1, 2, 4-8, and 10-27 are currently pending in the application. Claims 10, 11, 13, 15, 17, and 19-26 were previously withdrawn from consideration. Claims 1-9, 12, 14, 16, 18, and 27 are under consideration. Claims 1-9, 12, 14, 16, 18, and 27 stand rejected. Claim 9 is cancelled herein. Claim 1 is amended herein. New claims 29-32 are presented herein. Basis for new claims 29-31 can be found throughout the Specification and more particularly in original claims 1 and 9. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-8, 12, 14, 16, 18, and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicants note that the rejection of claim 3 is moot as claim 3 has been cancelled herein. Applicants respectfully traverse the remaining rejections as hereinafter set forth.

Although applicants do not agree that any of the claims lack enablement, to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1 has been amended to recite “wherein said cytoplasmic domain comprises at least a JAK binding site.” The Examiner notes that “with regards to fragments comprising a JAK binding site, it is not predictable whether or not other truncated cytokine receptors retaining a JAK binding site will remain functional in a recombinant receptor.” Final Office Action at page 10. Applicants respectfully submit that to satisfy the enablement requirement absolute predictability is not required; only that one of ordinary skill in the art be able to practice the invention without undue experimentation. Applicants respectfully submit that while extensive experimentation might be required to determine which recombinant receptors comprising JAK binding site would function, such experimentation would not be undue.

Two recent decisions by the Federal Circuit and the Board of Patent Appeals and Interferences (BPAI) have noted that, particularly in the biotechnological arts, even extensive experimentation in the norm and is not considered undue for the purposes of enablement. In *Falkner v. Inglis*, the Federal Circuit, in agreeing with the BPAI, notes that “the mere fact that

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the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have to be considered undue in this art. Indeed, great expenditures of time and effort were ordinary in the field . . .” 448 F.3d 1357, 1365 (Fed. Cir. 2006). In addition, the BPAI, the decision of *Ex parte Kubin*, noted that “[t]he amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those of skill in the art.” (83 USPQ2d 1410, 1416 (BPAI 2007)).

Applicants note that it is well within the capabilities of one of ordinary skill in the art to create multiple receptors comprising a JAK binding site according to claim 1 of the invention and that these recombinant receptors can be tested using the procedures and examples outlined in the Specification. Further, in light of the recent decisions in *Falkner* and *Kubin*, such creation and testing are considered routine in the biotechnological arts and are thus not undue.

In view of at least the foregoing, applicants respectfully submit that claim 1, as amended, is enabled. As such, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

In addition, applicants respectfully submit that claims 2-8, 12, 14, 16, 18, and 27 are enabled, *inter alia*, as depending from or otherwise comprising all the elements of enabled claim 1. Accordingly, applicants respectfully request the withdrawal of the rejections of claim 2-8, 12, 14, 16, 18, and 27 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-8, 12, 14, 16, 18, and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Applicants note that the rejection of claim 3 is moot as claim 3 has been cancelled herein. Applicants respectfully traverse the remaining rejections as hereinafter set forth.

Applicants respectfully note that a claim can meet the written description requirement under *Enzo Biochem, Inc. v. Gen-Probe Inc.* through the showing of “relevant identifying characteristics *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function

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and structure, or some combination of such characteristics. 296 F.3d 1316, 1324 (Fed. Cir. 2002) (emphasis added). Applicants respectfully note the added emphasis on “or” which applicants submit clearly indicates that one does not have to meet each and every one of the tests outlined by the *Enzo* court, but that any one of them can be met to satisfy the written description requirement.

Although applicants do not agree that any of the claims lack written description, to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1 has been amended to recite “wherein said cytoplasmic domain comprises at least a JAK binding site.” Applicants submit that JAK binding sites are well known in the art and that there is a disclosed correlation between structure and function for JAK binding sites. *See, e.g.* page 70 of Ihle et al., Jaks and Stats in signaling by the cytokine receptor superfamily, Trends Genet., Feb. 1995, pp. 69-74, Vol. 11, No. 2; submitted in and IDS field May 16, 2007. In light of the amendment, applicants respectfully submit that adequate written description for the recombinant receptor of claim 1 exists at least in that it has the functional characteristic of comprising a JAK binding site, which itself has a well known correlation between structure and function. Consequently, claim 1 should now be in condition for allowance. As such, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

In addition, applicants respectfully submit that claims 2-8, 12, 14, 16, 18, and 27 are adequately described, *inter alia*, as depending from or otherwise comprising all the elements of adequately described claim 1. Accordingly, applicants respectfully request the withdrawal of the rejections of claim 2-8, 12, 14, 16, 18, and 27 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

Double Patenting

Claims 1-9, 12, 14, 16, 18, and 27 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as assertedly being unpatentable over claims 1-2, 4-8, 11, 13, and 15 of co-pending application 10/751,072 in view of U.S. 5,885,779 and further in view of Carpenter *et al.*

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Since this is a provisional double patenting rejection, applicants will address the provisional rejection at the time the claims of the instant application or the claims of co-pending application no. 10/751,072 are in condition for allowance.

ENTRY OF AMENDMENTS

Pursuant to 37 C.F.R. § 1.116, applicants respectfully submit that the amendments presented herein should be entered as the amendments are made to expedite prosecution and are believed to remove issues for appeal and place the application in condition for allowance.

Applicants respectfully note that, as indicated at MPEP § 714.13(III), the Examiner is required to give the proposed amendment sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Applicants respectfully submit that the amendments avoid the rejections set forth in the Final Office Action, raise no issues of new matter, present no issues requiring further consideration or search, and do not present any additional claims. If the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested as they remove issues for appeal. As such, the applicants respectfully request that the amendments presented herein be entered and a Notice of Allowance issued.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

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Respectfully submitted,

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